

www.dot.gov/ost/dapc). ODAPC will notify HHS who will take appropriate action.

§ 40.107 Who may inspect laboratories?

As a laboratory, you must permit an inspection, with or without prior notice, by ODAPC, a DOT agency, or a DOT-regulated employer that contracts with the laboratory for drug testing under the DOT drug testing program, or the designee of such an employer.

§ 40.109 What documentation must the laboratory keep, and for how long?

(a) As a laboratory, you must retain all records pertaining to each employee urine specimen for a minimum of two years.

(b) As a laboratory, you must also keep for two years employer-specific data required in § 40.111.

(c) Within the two-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain the records for an additional period of time (*e.g.*, for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the records at the end of the two-year period.

§ 40.111 When and how must a laboratory disclose statistical summaries and other information it maintains?

(a) As a laboratory, you must transmit an aggregate statistical summary, by employer, of the data listed in Appendix B to this part to the employer on a semi-annual basis.

(1) The summary must not reveal the identity of any employee.

(2) In order to avoid sending data from which it is likely that information about an employee's test result can be readily inferred, you must not send a summary if the employer has fewer than five aggregate tests results.

(3) The summary must be sent by January 20 of each year for July 1 through December 31 of the prior year.

(4) The summary must also be sent by July 20 of each year for January 1 through June 30 of the current year.

(b) When the employer requests a summary in response to an inspection,

audit, or review by a DOT agency, you must provide it unless the employer had fewer than five aggregate test results. In that case, you must send the employer a report indicating that not enough testing was conducted to warrant a summary. You may transmit the summary or report by hard copy, fax, or other electronic means.

(c) You must also release information to appropriate parties as provided in §§ 40.329 and 40.331.

§ 40.113 Where is other information concerning laboratories found in this regulation?

You can find more information concerning laboratories in several sections of this part:

§ 40.3—Definition.

§ 40.13—Prohibition on making specimens available for other purposes.

§ 40.31—Conflicts of interest concerning collectors.

§ 40.47—Laboratory rejections of test for improper form.

§ 40.125—Conflicts of interest concerning MROs.

§ 40.175—Role of first laboratory in split specimen tests.

§ 40.177—Role of second laboratory in split specimen tests (drugs).

§ 40.179—Role of second laboratory in split specimen tests (adulterants).

§ 40.181—Role of second laboratory in split specimen tests (substitution).

§§ 40.183–40.185—Transmission of split specimen test results to MRO.

§§ 40.201–40.205—Role in correcting errors.

§ 40.329—Release of information to employees.

§ 40.331—Limits on release of information.

§ 40.355—Role with respect to other service agents.

Subpart G—Medical Review Officers and the Verification Process

§ 40.121 Who is qualified to act as an MRO?

To be qualified to act as an MRO in the DOT drug testing program, you must meet each of the requirements of this section:

(a) *Credentials.* You must be a licensed physician (Doctor of Medicine or Osteopathy). If you are a licensed physician in any U.S., Canadian, or Mexican jurisdiction and meet the other requirements of this section, you

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are authorized to perform MRO services with respect to all covered employees, wherever they are located. For example, if you are licensed as an M.D. in one state or province in the U.S., Canada, or Mexico, you are not limited to performing MRO functions in that state or province, and you may perform MRO functions for employees in other states or provinces without becoming licensed to practice medicine in the other jurisdictions.

(b) *Basic knowledge.* You must be knowledgeable in the following areas:

(1) You must be knowledgeable about and have clinical experience in controlled substances abuse disorders, including detailed knowledge of alternative medical explanations for laboratory confirmed drug test results.

(2) You must be knowledgeable about issues relating to adulterated and substituted specimens as well as the possible medical causes of specimens having an invalid result.

(3) You must be knowledgeable about this part, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom you evaluate drug test results, and you must keep current on any changes to these materials. The DOT MRO Guidelines document is available from ODAPC (Department of Transportation, 400 7th Street, SW., Room 10403, Washington, DC 20590, 202-366-3784, or on the ODAPC web site (<http://www.dot.gov/ost/dapc>)).

(c) *Qualification training.* You must receive qualification training meeting the requirements of this paragraph (c).

(1) Qualification training must provide instruction on the following subjects:

(i) Collection procedures for urine specimens;

(ii) Chain of custody, reporting, and recordkeeping;

(iii) Interpretation of drug and validity tests results;

(iv) The role and responsibilities of the MRO in the DOT drug testing program;

(v) The interaction with other participants in the program (*e.g.*, DERs, SAPs); and

(vi) Provisions of this part and DOT agency rules applying to employers for whom you review test results, includ-

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ing changes and updates to this part and DOT agency rules, guidance, interpretations, and policies affecting the performance of MRO functions, as well as issues that MROs confront in carrying out their duties under this part and DOT agency rules.

(2) Following your completion of qualification training under paragraph (c)(1) of this section, you must satisfactorily complete an examination administered by a nationally-recognized MRO certification board or subspecialty board for medical practitioners in the field of medical review of DOT-mandated drug tests. The examination must comprehensively cover all the elements of qualification training listed in paragraph (c)(1) of this section.

(3) The following is the schedule for qualification training you must meet:

(i) If you became an MRO before August 1, 2001, and have already met the qualification training requirement, you do not have to meet it again.

(ii) If you became an MRO before August 1, 2001, but have not yet met the qualification training requirement, you must do so no later than January 31, 2003.

(iii) If you become an MRO on or after August 1, 2001, you must meet the qualification training requirement before you begin to perform MRO functions.

(d) *Continuing Education.* During each three-year period from the date on which you satisfactorily complete the examination under paragraph (c)(2) of this section, you must complete continuing education consisting of at least 12 professional development hours (*e.g.*, Continuing Education Medical Units) relevant to performing MRO functions.

(1) This continuing education must include material concerning new technologies, interpretations, recent guidance, rule changes, and other information about developments in MRO practice, pertaining to the DOT program, since the time you met the qualification training requirements of this section.

(2) Your continuing education activities must include assessment tools to assist you in determining whether you have adequately learned the material.

(3) If you are an MRO who completed the qualification training and examination requirements prior to August 1, 2001, you must complete your first increment of 12 CEU hours before August 1, 2004.

(e) *Documentation.* You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are using or negotiating to use your services.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

§ 40.123 What are the MRO's responsibilities in the DOT drug testing program?

As an MRO, you have the following basic responsibilities:

(a) Acting as an independent and impartial "gatekeeper" and advocate for the accuracy and integrity of the drug testing process.

(b) Providing a quality assurance review of the drug testing process for the specimens under your purview. This includes, but is not limited to:

(1) Ensuring the review of the CCF on all specimen collections for the purposes of determining whether there is a problem that may cause a test to be cancelled (see §§ 40.199–40.203). As an MRO, you are not required to review laboratory internal chain of custody documentation. No one is permitted to cancel a test because you have not reviewed this documentation;

(2) Providing feedback to employers, collection sites and laboratories regarding performance issues where necessary; and

(3) Reporting to and consulting with the ODAPC or a relevant DOT agency when you wish DOT assistance in resolving any program issue. As an employer or service agent, you are prohibited from limiting or attempting to limit the MRO's access to DOT for this purpose and from retaliating in any way against an MRO for discussing drug testing issues with DOT.

(c) You must determine whether there is a legitimate medical explanation for confirmed positive, adulterated, substituted, and invalid drug tests results from the laboratory.

(d) While you provide medical review of employees' test results, this part does not deem that you have established a doctor-patient relationship with the employees whose tests you review.

(e) You must act to investigate and correct problems where possible and notify appropriate parties (*e.g.*, HHS, DOT, employers, service agents) where assistance is needed, (*e.g.*, cancelled or problematic tests, incorrect results, problems with blind specimens).

(f) You must ensure the timely flow of test results and other information to employers.

(g) You must protect the confidentiality of the drug testing information.

(h) You must perform all your functions in compliance with this part and other DOT agency regulations.

§ 40.125 What relationship may an MRO have with a laboratory?

As an MRO, you may not enter into any relationship with an employer's laboratory that creates a conflict of interest or the appearance of a conflict of interest with your responsibilities to that employer. You may not derive any financial benefit by having an employer use a specific laboratory. For examples of relationships between laboratories and MROs that the Department views as creating a conflict of interest or the appearance of such a conflict, see § 40.101(b).

§ 40.127 What are the MRO's functions in reviewing negative test results?

As the MRO, you must do the following with respect to negative drug test results you receive from a laboratory, prior to verifying the result and releasing it to the DER:

(a) Review Copy 2 of the CCF to determine if there are any fatal or correctable errors that may require you to initiate corrective action or to cancel the test (see §§ 40.199 and 40.203).

(b) Review the negative laboratory test result and ensure that it is consistent with the information contained on the CCF.

(c) Before you report a negative test result, you must have in your possession the following documents: